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Determining the Minimal Clinically Important Difference and Responsiveness of the Dermatology Life Quality Index (DLQI): Further Data

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Key Words
DLQI · MCID · Responsiveness · Minimum clinically important difference · Skin disease

Abstract
Aims: To determine the minimal clinically important difference (MCID) of the Dermatology Life Quality Index (DLQI) and its responsiveness to change in inflammatory skin diseases. ***Methods:*** A longitudinal study: at stage 1, patients completed the DLQI and a disease severity global question; at stage 2, a global rating of change in quality of life (QoL; Global Rating of Change Questionnaire, GRCQ) was added and used as an anchor to measure the MCID of the DLQI. ***Results:*** 192 patients completed stage 1 and 107 completed stage 2. The mean DLQI score at stage 1 was 9.8 and 7.4 at stage 2 with a mean change of 2.4 ($p < 0.0001$). 31 patients experienced a 'small change' in their QoL (±3 and ±2) on the GRCQ. The mean corresponding change in DLQI scores was 3.3, which is regarded as the approximate MCID. ***Conclusions:*** Previous estimates of the MCID of the DLQI have varied from 3 to 5. Although this study demonstrated a MCID of 3.3, we recommend that the MCID in inflammatory skin diseases should be 4.

Introduction

Quality of life (QoL) assessment has become an important outcome measure in clinical trials as well as in routine clinical practice, and such information is also used by health policy makers in health care resource allocation and reimbursement decisions. To be clinically useful, QoL measurement instruments must have demonstrated psychometric properties such as validity, reliability and responsiveness to change. Responsiveness to change is crucially important for instruments designed to measure change over time. The responsiveness of an instrument to change is directly related to the magnitude of the change in a respondent's QoL score [1]. However, the statistical significance of a change in score does not necessarily imply that the score change is also clinically important [2]. The interpretation of a change in score of a QoL measure is less intuitive than of a clinical measure (e.g. blood pressure); this of course does not imply that it is less precise [3]. This highlights the need to define for QoL measures the minimal change in score considered important by patients and by physicians.

The minimal clinically important difference (MCID) has been defined as 'the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's manage-

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Table 1. Previous studies demonstrating the MCID of the DLQI scores (adapted from Basra et al. [7])

Reference	Country	Patients, n	Disease	Method used	Results
17	UK	215	Inflammatory skin diseases	Anchor-based (overall QoL change question used as anchor)	A score change of 5 = a little better
18	USA	A = 403 B = 423	CIU	Anchor-based Distribution-based (SEM; half SD)	Anchor-based = 2.97–3.21 Distribution-based = 2.24–3.1
19	USA, Canada	147	Psoriasis	Anchor-based (3 methods) Distribution-based (SEM; half SD)	Anchor-based = –4.05 to –6.95 SEM = 2.33 Half SD = 3.59
20	USA	667	Hyperhidrosis	Anchor-based (HDSS used as anchor) Distribution-based (ES, SEM)	Anchor-based = 2.2–5.0 Distribution-based: axillary hyperhidrosis = 2.8–4.6 palmar hyperhidrosis = 3.0–4.6
21	USA	147	Psoriasis	Anchor-based (PASI and PGA used as anchors)	MCID = 3.2

CIU = Chronic idiopathic urticaria; SEM = standard error of the mean; SD = standard deviation; HDSS = Hyperhidrosis Disease Severity Scale; ES = effect size; PASI = Psoriasis Area and Severity Index; PGA = Psoriasis Global Assessment.

ment' [4]. From the patient's point of view, a meaningful change in QoL may be one that reflects a reduction in symptoms or improvement in function. However, a meaningful change for the physician may be one that indicates a change in the treatment or in the prognosis of the disease [5].

The Dermatology Life Quality Index (DLQI) was developed in 1994 [6, 7] to measure dermatological patients' QoL and is the most commonly used measure in clinical trials [8, 9]. The DLQI is a reliable and valid instrument [7, 10, 11]. However, it has fallen short in some other aspects of psychometric performance in particular unidimensionality and item bias [12–15]. Hongbo et al. [16] have demonstrated a banding system to aid the interpretation of DLQI scores, but a frequent question still arises: what does a specific improvement, such as 2, 5 or 6 points, in a DLQI score mean to a patient (and to the physician)? Does it indicate that patients have noticed an important change, or do they feel the improvement was small and not noticeable? The MCID of the DLQI needs to be known to answer these questions.

A range of values of the DLQI MCID has been estimated in different dermatology conditions (table 1): the commonly accepted value of 5 was based on a preliminary study published as an abstract [17]. The aims of this study were to determine the MCID of the DLQI in skin conditions using the anchor-based approach and to assess the DLQI's responsiveness to change. Establishing more accurately the MCID of the DLQI will assist planning and interpretation of clinical trials (e.g. sample size calculations).

Methods

Patients were recruited from the dermatology outpatient clinic at the University Hospital of Wales, Cardiff. The study was approved by the Research and Development Department of the Cardiff and Vale National Health Service Trust. All patients gave their written informed consent.

Inclusion criteria were: adult first time referral and follow-up patients with different skin conditions excluding skin cancers, patients starting new treatment or who had changed treatment following therapy failure. Patients were excluded if suffering from significant comorbidity, if they had a non-inflammatory skin condition or if they were aged under 16 years.

Study Design

There were two stages. In stage 1, the participant's age, gender, disease diagnosis, disease duration, previous treatment and any new prescribed treatment were recorded. Patients were asked to complete the DLQI and the global question (GQ) about their self-assessment of skin disease severity. Stage 2 was conducted 1–3 months after stage 1 in part by in-person completion of follow-up questionnaires at the routine follow-up appointments and in part by postal questionnaires sent to patients. In order to maximize the response rate, either a phone call or letter reminder was used. Patients were asked to complete the DLQI and the GQ again. They were also asked to complete the Global Rating of Change Questionnaire (GRCQ), recording any overall change in their QoL since stage 1.

DLQI

The DLQI is a short QoL instrument [6, 7] that can be used in all skin diseases, allowing comparison between them. It is self-administered with a mean completion time of 2 min [22]. It consists of 10 questions concerning impact of skin diseases on different aspects of patient's QoL over the last week. The DLQI items include symptoms and feelings, daily activities, leisure, work or school, personal relationships and the side effects of treatment. Each item is scored on a 4-point scale: not at all/not relevant, a little, a lot and very much. Item scores (0–3) are added to give a total score (0–30); higher scores indicate greater impairment of QoL.

GQ

The GQ gives the patient's self-assessment of skin disease severity on a 0–10 visual analogue scale; 0 indicates clear skin and 10 that the condition was the worst possible.

GRCQ

The GRCQ [4], used as an anchor, allows patients to give a self-assessment of the change since baseline assessment in, for example, overall QoL or severity of skin condition, whether it has improved, remained the same or deteriorated. It has a 15-point scoring system with responses ranging from a very great deal better (+7) to no change (0) to a very great deal worse (–7). The GRCQ with a 15-point scoring system was chosen to maximize the sensitivity of the responses. Respondents with scores of 0, –1 or 1 are classified as unchanged or having a small but unimportant change. Respondents whose scores are 2, 3, –2 or –3 are considered to have experienced a small change equivalent to the minimal important difference. Those with scores of 4, 5, –4 or –5 are considered to have experienced a moderate change, and those with scores of 6, 7, –6 or –7 are considered to have experienced a large change [3, 4]. The question posed was: 'Since your first clinic visit, has there been any change in overall quality of life related to your skin disease?'

Data Analysis

The data were processed using SPSS® Version 12 for Windows. The anchor-based method was used on the longitudinal data to determine the MCID of the DLQI. The scores for each category of the GRCQ were compared with the mean change in DLQI scores from the first assessment at the initial clinic visit (stage 1) to the second assessment (stage 2) for each patient. Subjects whose GRCQ scores were 2, 3, –2 and –3 were considered to have experienced a small change in their QoL which would be equivalent to the MCID [3, 4]. In subjects showing a GRCQ score change of more or less than 0, the change in DLQI scores was combined by changing the sign of the scores for those whose QoL worsened [3].

A distribution-based approach was used to understand the responsiveness of the DLQI to change by identifying the magnitude of difference in the DLQI score between the two stages. We used a paired samples t test to assess whether the DLQI could detect change that occurred from stage 1 to stage 2. The following distribution-based methods were used to detect the magnitude of that change in the DLQI scores:

Effect size (ES) was calculated as a ratio of the raw DLQI score difference from the first to the second assessment to the standard deviation at the first assessment. An ES of 0.2 is considered small, 0.5 moderate and 0.8 large [23]. The standardized response mean (SRM) was calculated as the ratio of the raw DLQI score difference from the first to the second assessment to the standard deviation of that difference.

Table 2. List of skin diseases in stage 1

Skin conditions	n	%
Psoriasis	97	50.5
Eczema	24	12.5
Acne	42	21.9
Rosacea	4	2.1
Blistering	1	0.5
Psychosis barbae	2	1.0
Adverse drug reaction	3	1.6
Lichen simplex	1	0.5
Hidradenitis suppurativa	4	2.1
Polymorphic light eruption	1	0.5
Erosive pustular dermatosis	1	0.5
Bullous pemphigoid	1	0.5
Reactive lymphoid infiltrate	1	0.5
Lupus	1	0.5
Allergic reaction	2	1.0
Non-specific skin rash	3	1.6
Diabetic wound	1	0.5
Erythrokeratodermia variabilis	1	0.5
Pityriasis versicolor	1	0.5
Seborrhoeic dermatitis	1	0.5

Table 3. Demographic characteristics of study participants at stage 1 (n = 192)

Age, years	
Mean ± SD	38.7±17.2
Range	16–91
Gender	
Male	80 (41.7%)
Female	112 (58.3%)
Marital status	
Single	107 (58.5%)
Married	67 (36.6%)
Ethnicity	
Caucasian	170 (92.0%)
Asian	5 (2.7%)
Education	
Primary	4 (3.1%)
Secondary	53 (41.4%)
University	43 (33.6%)
Employment status	
Full-time employed	26 (37.7%)
Part-time employed	7 (10.1%)
Unemployed	13 (18.8)
Retired	23 (33.3%)

Table 4. DLQI item and total score at stages 1 and 2 and showing the mean change with ES and SRM

DLQI items	Stage 1 score	Stage 2 score	Mean change	p value	ES	SRM
(1) Symptoms	1.5	1.1	0.4	0.0001	0.39	0.4
(2) Psychological	1.5	1.1	0.4	0.0001	0.37	0.37
(3) Daily activities	0.8	0.5	0.3	0.002	0.26	0.3
(4) Clothes	1.5	1.1	0.4	0.001	0.25	0.32
(5) Social/leisure activities	1.1	0.8	0.3	0.002	0.25	0.31
(6) Sports	0.9	0.7	0.2	0.01	0.21	0.25
(7) Work/study	0.8	0.5	0.3	0.01	0.23	0.25
(8) Relationships	0.6	0.5	0.1	0.12	0.12	0.15
(9) Sex life	0.4	0.4	0.01	0.12	0.01	0.01
(10) Treatment effects	0.93	0.85	0.08	0.89	0.08	0.08
Total score	9.8	7.4	2.4	0.0001	0.3	0.4

Results

Patients (n = 192) aged 16–91 years (male = 80; female = 112), suffering from 20 different skin conditions (table 2), ranging from acute to chronic, completed the DLQI and the self-assessed disease severity GQ at stage 1 (table 3). The commonest conditions were: psoriasis (50.5%), acne (21.9%) and eczema (12.5%). The mean patient age was 38.7 years (SD = 17.2); the majority were Caucasians (92.0%). The mean disease duration was 152.6 months (SD = 163.3). 107 patients (55.7%) completed the DLQI, GQ and GRCQ at stage 2. The mean time interval from the first to the second administration was 77.8 days (SD = 68).

The mean DLQI score at stage 1 was 9.3 (SD = 7.3), and the mean GQ score was 5.7 (SD = 2.5). Female patients had higher DLQI scores than males (female mean score = 10.2, SD = 7.5; male = 8.1, SD = 6.8; p = 0.049) and the self-assessed disease severity GQ scores (female mean score = 6.1, SD = 2.4; male = 5.2, SD = 2.6; p = 0.01). The mean DLQI score at stage 2 (n = 107) was 7.4 (SD = 7.1) and the GQ score 4 (SD = 2.4). There was no significant difference in DLQI scores between male (mean score = 5.9, SD = 6.6) and female patients (mean score = 8.4, SD = 7.3; p = 0.06) but there was between their self-assessed disease severity GQ scores (male mean score = 3.1, SD = 2.4; female = 4.6, SD = 2.3; p = 0.001). There was a high correlation between patients' mean DLQI scores and their self-assessed disease severity GQ at both stage 1 ($r_s = 0.62$; $p < 0.0001$) and stage 2 ($r_s = 0.67$; $p < 0.0001$).

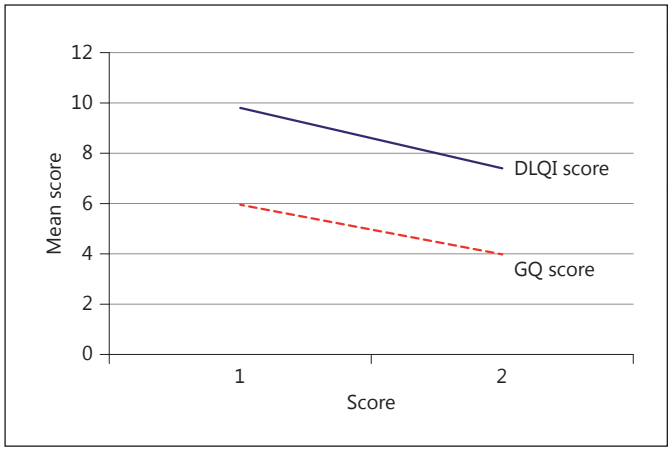
The main differences between responders (n = 107; males = 40.2%; females = 59.8%) and non-responders (n = 85; males = 43.5%; females = 56.5%) include: mean age of responders = 41.8 years and mean age of non-responders = 34.9 years (p = 0.005); mean baseline DLQI score of responders = 9.8 and mean baseline DLQI score of non-responders = 8.8 (p = 0.36); mean baseline self-assessed global disease severity score of responders = 6.1 and of non-responders = 5.3 (p = 0.03).

The most highly scoring DLQI items at both stages were items 1, 2 and 4 concerning physical symptoms, psychological impact and impact on clothes, while the lowest scoring item was item 9 asking about sexual difficulties (table 4). Correspondingly, the most significant differences according to the magnitude of change between the two stages were reported for items 1, 2 and 4 and the smallest change was observed for item 9, followed by item 10 (table 4).

Responsiveness to Change of the DLQI

The responsiveness analysis, using the paired samples t test, showed that the DLQI was responsive to change. The mean DLQI score of 107 patients at stage 1 was 9.8 (SD = 7.8) and 7.4 (SD = 7.1) at stage 2 with a mean change of 2.36 ($p < 0.0001$). The mean disease severity GQ score at stage 1 was 5.95 (SD = 2.5) and 3.98 (SD = 2.4) at stage 2 with a mean change of 1.97 ($p < 0.0001$). Figure 1 shows the trend in the reduction of both the DLQI and the GQ scores from stage 1 to stage 2 implying that with reduction in patient self-assessed disease severity there was a parallel improvement in their QoL measured by the DLQI, shown by reduction in DLQI scores.

Two distribution-based methods were used to identify the magnitude of the change in the DLQI scores: the ES of the DLQI change score was 0.3 while the SRM was 0.4, both indicating a small effect according to Cohen's crite-



Color version available online

Fig. 1. Responsiveness to change – DLQI and GQ score change from stage 1 to stage 2.

ria [20]. Similar statistics were shown for all 10 items of the DLQI with a significant change in score from stage 1 to 2 except for items 8, 9 and 10 (table 4).

MCID of the DLQI Score

Based on the responses to the GRCQ, patients were divided into 4 categories: those having experienced no change, a small change, moderate change and large change. 31 patients experienced a 'small change' in their QoL (±3 and ±2) on the GRCQ. The mean corresponding change in DLQI scores was 3.3 (SRM = 0.27; ES = 0.21), which could be regarded as the MCID of the DLQI scores. The mean DLQI scores in patients with 'no change', 'moderate' and 'large' change on the GRCQ were 2.7 (n = 23; SRM = 0.01, ES = 0.004), 4.4 (n = 25; SRM = 0.46, ES = 0.39) and 6 (n = 28; SRM = 0.69, ES = 0.67).

Discussion

Although the banding descriptors of DLQI scores [16] have allowed one clinical interpretation of DLQI scores, it was crucial that the MCID should also be established, to facilitate the understanding of what change in score is clinically meaningful, and that would indicate the need for a change in patients' management. To our knowledge, this is the first comprehensive study to establish the MCID of the DLQI in general inflammatory skin disorders with the exception of skin cancers and benign skin lesions. A preliminary study published as an abstract was the first attempt to determine the MCID of DLQI scores [17] but was limited due to methodological shortcomings and small sample size (low patient numbers showing change in QoL).

Although this study has demonstrated a MCID of 3.3, from the practical point of view we recommend that the MCID of the DLQI in skin diseases, excluding skin lesions and skin cancers, should be taken as 4. Therefore, differences in scores smaller than the MCID value of 4 should not be considered clinically important whatever their statistical significance may be. This magnitude of change (i.e. 4) could be caused by a respondent answering 1 response category (out of 4) differently on at least 4 out of the 10 items of the DLQI. A change in score of, say, 8 would clearly represent a larger difference. The mean changes in the DLQI scores demonstrate a somewhat orderly pattern in the GRCQ for no change, small change, moderate change and large change. However, the magnitudes of differences in the DLQI mean score for each category were not equal. There could be several reasons for this disparity; for example, the global rating scale (e.g. GRCQ) is a subjective measure and does not represent a criterion standard for assessment of change, but allows errors having a non-systematic pattern, such as in our case of unequal differences in scores between the four categories. Moreover, global assessment of change has been criticized as a method of recording change due to recall bias, as many patients do not remember their baseline or pretreatment QoL experience, thereby causing discrepancy between the two assessments [5, 24], and therefore the validity and reliability of global assessment of change have been debated [25]. Nevertheless, global assessment scales such as the GRCQ have been proven to be sensitive to both positive and negative changes, the very purpose of their use in this study [26]. Because of the methodology applied in our study, combining the responses from patients with both improvement and deterioration in their QoL scores, the data are applicable for improvement and deterioration. There is evidence suggesting that positive and negative change can be treated as equivalent [3].

To assess the MCID using the anchor-based approach, different anchors or criteria could be used to identify improvement or deterioration. These anchors or criteria could be clinical end points or patient-rated global change or a combination of these [27]. Given the inclusion of 20 different skin conditions in our sample, many having their separate and specific clinical end points, the first or the third approach was not considered feasible. Although the choice of a subjective assessment tool such as the GRCQ as an external anchor is not ideal, it was considered the most suitable approach given the multitude of skin diseases and the lack of a single objective assessment tool. Moreover, in

order to use a GRCQ as an anchor, it is recommended to have at least a moderate correlation with the questionnaire used. The value of correlation between the GRCQ and DLQI in our analysis was found to be 0.32 ($p = 0.001$).

The proposed value of the MCID fits with previous reports [17–21]. The first attempt to determine the MCID of the DLQI scores [17] had methodological shortcomings and a small sample size. The MCID for inflammatory skin diseases was given as 5 [17] while for stable plaque psoriasis it was in the range of 2.3–5.7 [19]. The MCID in chronic idiopathic urticaria was in the range of 2.24–3.10 [18]. The value of 4 as determined by our data is in the same range but was based on a cohort of patients with many different kinds of predominantly inflammatory skin conditions. Confidence in a specific MCID value should evolve over time as evidence gathers from additional research [27].

Many therapy guidelines using the DLQI have used a score change of 5 as a critical change to influence clinical decision taking [28]. The evidence that the DLQI MCID should be considered to be 4 does not invalidate these guidelines; on the contrary, it provides further reassurance that a score change of 5 does definitely represent a clinically significant change.

One limitation of our study is the subjective arbitrary nature of the anchor, the GRCQ. The patients' self-rating of change may not be accurate to represent a criterion standard for change in the DLQI (or other outcome measures). This is because perception of change varies from person to person [4]. Moreover, the descriptive terms used in the GRCQ and the scaling of the responses may affect respondents' choice and hence the clinically important difference [2]. Although the GRCQ is not a gold standard, it has been used successfully as an anchor in studies determining the MCID of QoL instruments [3]. The sample size of our study, especially at follow-up, could be considered modest. However, past studies have used sample sizes as small as 39 when using the anchor-based approach [3]. Moreover, there is no consensus on the amount of data required as supportive evidence for the MCID of a QoL measure [27]. The distribution-based data obtained in this study should not have been affected by the sample size, as ES and SRM calculations are independent of sample size [5].

It should also be noted that there are many studies that have examined the relationship between objective sign-based measures of skin disease and QoL impairment. Although our study has shown a correlation between self-assessed disease severity (assessed by the GQ), the clinical severity of skin disease does not always correlate with the impact on the patient's quality of life assessed by, for example, the DLQI [29, 30]. Although, at a population and individual level, it is sometimes possible to demonstrate a correlation, it is not possible to predict QoL impairment from objective measures, because a variety of individual patient psychological and personal factors also influence the overall QoL impairment.

Our study findings have clinical implications. The estimation of the MCID of the DLQI is not only useful for judging the clinical benefit (in terms of meaningful change over time) of individual treatments and for comparing the cost-effectiveness of two treatments in clinical trials, but it can also provide a basis for sample size calculation for longitudinal studies [31]. This information can also assist patient classification according to changes in QoL over time, depending on whether the DLQI scores changed by the corresponding/proportionate factor of the MCID.

Conclusion

In order to be accepted as evidence of treatment effectiveness, a QoL measure must demonstrate evidence concerning its psychometric properties including reliability, validity and responsiveness to change. This study has demonstrated the responsiveness of the DLQI to change and its MCID. These are two key components needed for patient-reported outcome labelling and promotional claims as set out by many regulatory authorities including the Federal Drug Agency in the USA [32]. For all practical purposes, the MCID value of 4 is proposed for all types of skin diseases excluding skin lesions and skin cancers. The availability of a single MCID value should provide a useful tool for both clinicians and researchers in judging the effectiveness of interventions.

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Disclosure Statement

A.Y.F. is a joint copyright holder of the DLQI. The Department of Dermatology and Wound Healing, Cardiff University School of Medicine, receives some funding from the use of the DLQI.

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